Clinical effectiveness of subsensory sacral neuromodulation in adults with faecal incontinence: the SUBSoNIC crossover RCT and mechanistic study

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Plain language summary

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Plain language summary

A treatment called sacral neuromodulation is commonly offered to adults experiencing bowel (faecal) incontinence. A battery powered unit is implanted into the lower back in the region of the sacrum (tailbone). This is connected to a specially developed lead with electrodes that rest on the nerves of the lower spine. This stimulator then continuously sends electrical impulses to the nerves and muscles that control the lower bowel (rectum and anus). The aim is to improve bowel control.

Previous studies have reported a great benefit of sacral neuromodulation in some patients, but others have little or no response. The SUBsensory Sacral Neuromodulation for InContinence trial recruited 39 patients (of 90 intended) who met the current national criteria for sacral neuromodulation. It compared the effect on numbers of weekly faecal incontinence episodes with the device either on (active) or off (sham) using a special study design called a randomised crossover trial. All participants had the device on and off for 16 weeks in random order (crossing over in the middle). Using stimulation below the level that can be felt (subsensory), both the patients and the research team were unaware of whether the stimulator was on or off (called double blinding).

Due to COVID-19, only 16 patients had complete data for analysis, which was much less than the intended number of 90. The results showed that patients experienced reductions in faecal incontinence episodes during both on and off periods (i.e. there was a strong placebo effect). However, slightly greater effects were seen during the on period suggesting a possible genuine biological effect of sacral neuromodulation. The study also showed that the way we record symptoms during research trials for example with paper bowel diaries needs improvement, as the bowel diaries were not fully completed by some participants. Although this is the first double-blind trial of its kind for sacral neuromodulation, all conclusions must bear in mind the poor recruitment and retention of patients.

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